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UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE COMPANY, INC.,

Plaintiff/ Counterclaim-Defendant

VS.

INTUITIVE SURGICAL, INC.,

Defendant/ Counterclaim-Plaintiff. Case No.: 3:21-cv-03496-VC

MOTION OF INTUITIVE SURGICAL, INC. TO EXCLUDE THE EXPERT OPINIONS OF KURT HUMPHREY

Case No.: 3:21-cv-03496-VC

Hearing Date: June 8, 2023 Hearing Time: 1:00 PM Hearing Place: Courtroom 4

Judge: Hon. Vince Chhabria

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NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on June 8, 2023, at 1:00 p.m., or as soon thereafter as available, in the courtroom of the Honorable Vince G. Chhabria, located at 450 Golden Gate Avenue, Courtroom 4, 17th Floor, San Francisco, CA 94102, Defendant/Counterclaimant Intuitive Surgical, Inc. will and hereby does move for an order excluding certain testimony of Kurt Humphrey, proffered as an expert witness for Plaintiff/Counterclaim-Defendant Surgical Instrument Services Company, Inc.

This Motion is based on this Notice of Motion, the Memorandum of Points and Authorities, the accompanying Declaration of Kathryn Cahoy and attached exhibits, any reply or other supplemental briefing and/or evidence submitted by Intuitive Surgical, Inc., and the oral argument of counsel.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION AND STATEMENT OF ISSUES

As anyone who has furiously fiddled with the connection for a plug-in phone charger or headphone jack will tell you, wireless technology can be an improvement over wired technology. A decade ago, Intuitive made this upgrade for its new generation of X/Xi EndoWrists, which transmit certain information to the da Vinci system using a wireless communication channel. Intuitive encrypted that wireless channel, rather than leaving it vulnerable to remote tampering, and employed other cybersecurity mitigation measures to guard against potential tampering. Doing so was consistent with FDA guidance, which recognizes the importance of cybersecurity measures for medical devices given safety and effectiveness risks.

Plaintiff SIS has submitted a report from Kurt Humphrey, a ceramics engineer who states he is an expert in reverse engineering of microprocessors. Humphrey devotes an entire section of his report to an argument that he has divined Intuitive's motives, intent, and reasoning for upgrading the chip in the X/Xi, contending that Intuitive's "primary concern" was preventing third parties from resetting the use counter. However, motive, intent, and state of mind are not proper subjects of expert testimony. Moreover, Humphrey's improper opinions on motive rest on his regurgitation of a handful of quotes

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taken from produced documents, interspersed with his personal interpretation of these documents.

Those musings do not constitute expert methodology and would not assist a trier of fact.

Second, returning to an opinion he offered in the *Rebotix* case, Humphrey opines that it is "feasible" for a third party to break the encryption on the use counter for X/Xi EndoWrists and reprogram the chip to override the use limit it is programmed to implement. But the content of Humphrey's opinion has changed dramatically in the 20 months since he submitted his previous report. In *Rebotix* Humphrey relied heavily on aspects of a report submitted by another expert, who explained how Rebotix purportedly could re-set the X/Xi use counter. Humphrey opined that the other expert's proposed process would be simple, straightforward, and easier than the programming for the S/Si re-sets in key respects. Now Humphrey no longer accepts key assertions in that other report, acknowledging that breaking the X/Xi encryption will require substantially more time and resources than was required to create a process to reset S/Si EndoWrists and admitting he is unsure of the accuracy of key assumptions underlying the proposed approach. Humphrey still contends that breaking the encryption for X/Xi EndoWrists is feasible (although no one, including Rebotix, has established a process for doing it). But he admits that software, which includes encryption and programming, is not his area of expertise, so he lacks the qualifications needed to support that opinion or any methodology that would make his opinion reliable.

Finally, although no third-party reset company has yet established a process for breaking the encryption and re-setting the use counters on X/Xi EndoWrists, Humphrey offers several conflicting timeframes for when that allegedly could have been accomplished in the past. SIS's damages expert then relies on some of these dates to justify SIS's outlandish damages claims, over 95% of which stem from still-nonexistent X/Xi re-set technology. Humphrey's timing estimates for hypothetical X/Xi re-set sets should be excluded because they are arbitrary, depending on nothing more than his say-so. ¹

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¹ For the avoidance of doubt, Intuitive reserves the right to raise additional objections to admissibility at a later date. This brief focuses on key issues fit for resolution at this stage of the case.

II. FACTUAL BACKGROUND

A. X/Xi Wireless Upgrade, Encryption, and FDA Cybersecurity Guidance

Intuitive has made several generations of da Vinci surgical robots and corresponding generations of EndoWrist instruments, including the Generation 3 EndoWrists compatible with S and Si robots and the newer Generation 4 EndoWrists compatible with X and Xi robots. The upgraded Generation 4 EndoWrists first began being sold after they received regulatory clearance in 2014. *See* Cahoy Dec. Ex. 1 at 24:20-25:1.

Among other improvements, the X/Xi EndoWrists were upgraded to include a wireless communication channel for transmitting information, including instrument identification, calibration data, and use counts, between the EndoWrist and the da Vinci robot. *See* Cahoy Dec. Ex. 2 at 56:4-61:15; 109:6-22. S/Si EndoWrists transmitted information through a direct wired connection, implemented in a "Dallas" chip. For X/Xi EndoWrists, Intuitive upgraded to a radio frequency identification ("RFID") interface – a form of wireless communication. *See* Cahoy Dec. Ex. 3 at 27:20-28:8. As a general matter, wireless connections tend to be simpler to manufacture and more durable and consistent, and the specific RFID Intuitive used offered various functional improvements over the previous Dallas chip. *See id.*; Cahoy Dec. Ex. 4 at ¶ 58.

However, the upgrade to wireless connectivity also necessitated new cybersecurity protections. When information is sent through an unencrypted wireless channel, it can be remotely intercepted and altered by third parties who are not physically present in the operating room. *See* Cahoy Dec. Ex. 4 at ¶¶ 33-41. Cybersecurity concerns like these have long been of interest to the FDA, which has published several guidance documents emphasizing the need for device makers to account for cybersecurity in the clearance process. For example, the FDA published software-related guidance as early as 1999, and more detailed guidance on "Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software" in 2005. Consistent with (and citing to) that and other guidance, the FDA instructed

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² See "Off-The-Shelf Software Use in Medical Devices, Guidance for Industry and Food and Drug Administration Staff," originally issued Sept. 9, 1999, https://www.fda.gov/media/71794/download;

Intuitive in August 2013 to respond to questions about cybersecurity as part of the X/Xi clearance process. *See* Cahoy Dec. Ex. 5 at ¶¶ 246-54. Intuitive submitted a cybersecurity risk assessment and pointed to encryption as a key mitigation measure against modification or injection of false instrument data that could lead to incorrect motion control and use of instruments beyond their tested life. *See id.* ¶ 251; Cahoy Dec. Ex. 4 at ¶ 52. FDA subsequently cleared the devices, granting 510(k) clearance in March of 2014.³

B. Third Parties' X/Xi Reverse Engineering Efforts and Humphrey's Report

In 2016, two years after the X/Xi release, Rebotix began resetting S/Si EndoWrist usage counters in Europe. *See* Cahoy Dec. Ex. 6 at ¶ 57. It entered the U.S. in 2018, through its distributor Restore, but later broke its relationship with Restore and began working with plaintiff SIS as a distributor in 2019. *See* Cahoy Dec. Ex. 7 at p. 10, 12. None of these entities ever had a process to reset X/Xi EndoWrists, although they have tried to do so for years. *See* Cahoy Dec. Ex. 8 at 38:20-39:12.

Despite its inability to reset X/Xi EndoWrists, Rebotix sought damages related to X/Xi in its lawsuit against Intuitive and retained Humphrey, a ceramics engineer by training, as an expert to support that theory. *See* Cahoy Dec. Ex. 9, Attachment 3. In that July 2021 report, Humphrey concluded that "Rebotix will have the capability to implement a reset of the usage counter on the X/Xi EndoWrists." *Id.* at ¶ 47. Humphrey's report relied heavily on a parallel report by Gwen Mandel, citing it dozens of times. *See, e.g., id.* ¶ 56, 59, 67, 78. Ms. Mandel's father, Stan Hamilton, is one of the part-owners of Rebotix. *See* Cahoy Dec. Ex. 10 at 44:8-23. Relying on Ms. Mandel for key assumptions given that his "expertise tends to be more in the hardware, not the software side of things," Cahoy Dec. Ex. 10 at 124:7-15, Humphrey alternatively described aspects of the Rebotix process as "simple," "straightforward," and "easier" than for the S/Si. Cahoy Dec. Ex. 9, Attachment 3 at ¶¶ 69-76. The

[&]quot;Guidance for Industry, Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software," Jan. 14. 2005, https://www.fda.gov/media/72154/download.

³ See "Intuitive Surgical Announces New da Vinci(R) Xi(TM) Surgical System," Apr. 1, 2014, https://tinyurl.com/48ch5d72.

Rebotix court, reviewing a challenge to the combination of opinions from Mandel and Humphrey, denied Intuitive's *Daubert* motion as to them. Cahoy Dec. Ex. 11.

Fast forward more than a year and a half, and Humphrey, hired this time by SIS's counsel, still opines that a process to break the encryption on the X/Xi chip and design a way to reprogram the use counter is feasible, but he no longer describes it as simple, straightforward, and even "easier" than for the Si. *See* Cahoy Dec. Ex. 9, Attachment 3 at ¶¶ 47, 70. Rather, he concedes that, "as compared to the encryption used for the use counter of the Si EndoWrists, the Xi encryption requires substantially more time and resources to reverse engineer." *See* Cahoy Dec. Ex. 9 at ¶ 14. When questioned about core assertions in Mandel's report on which he had previously relied, he acknowledged uncertainty about them, *see* Cahoy Dec. Ex. 10 at 70:1-71:3; yet he identifies no new source of true expertise on those points upon which he relies.

Humphrey's new report also adds hypothetical timeframes for when in the past reverse engineering of X/Xi EndoWrists would have been possible, even though it has not actually happened in the real world. Between his new report and a separate apparent conversation with SIS's damages expert that the latter used as a basis for his calculations, Humphrey has offered four different dates: "any time in the last five years," "at least as early as 2019," "January 1, 2021," and "January 1 2022." *Id.* ¶¶ 15, 36; *see* Cahoy Dec. Ex. 7 at p. 5 n.19. When asked for the basis of his opinions on timing, all Humphrey could offer was: "Just that there is nothing that – no evidence I've seen that inherently shows this work couldn't have been started much earlier." Cahoy Dec. Ex. 10 Humphrey Dep. at 94:3-95:1.

Humphrey also adds another new opinion in this case: he contends that Intuitive's reasoning and motive for upgrading to an encrypted RFID interface for X/Xi instruments was to "prevent modification of the use counter" by third parties like SIS. *See* Cahoy Dec. Ex. 9 at § VI, ¶¶ 53, 59; *See* Cahoy Dec. Ex. 12 at ¶ 14. He bases these motive and intent opinions, not on any identified expertise in discerning corporate motives, but rather on a recitation of selective quotations from a handful of internal emails and documents. *See* Cahoy Dec. Ex. 9 at ¶¶ 52-55.

III. LEGAL STANDARD

Expert witness testimony must (1) come from a qualified expert; (2) be helpful to the factfinder; (3) be based on sufficient facts or data; (4) use reliable principles and methods; and (5) reliably apply those principles and methods to the facts of the case. Fed. R. Evid. 702. A court's "gatekeeping" role requires evaluating both the reliability of the expert's methods and the connection between their conclusions and the facts on which those conclusions are based. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). The party proffering expert testimony has the burden of proving admissibility. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 n. 10 (1993).

IV. ARGUMENT

A. Humphrey's Speculation About Intuitive's Motivation for Design Changes Should Be Excluded.

Humphrey contends that Intuitive's primary motive in upgrading to an encrypted RFID communication channel for X/Xi EndoWrists was to block third parties like SIS. *See* Ex. 9 at ¶¶ 16, 47-59; Ex. 12 at ¶ 14. He devotes an entire section of his report to the purported reason Intuitive employed encryption on the X/Xi chip. Ex. 9 § VI. This section is rife with speculation in a variety of forms: he claims that the change increased Intuitive's revenues, that Intuitive was "unconcerned about any other data stored on the RFID chip," and that Intuitive's "primary concern" in encrypting the chips was stopping third-parties from adding lives to the EndoWrist. *See id.* at ¶¶ 53, 55, 59. All of the opinions in this section should be excluded because (1) corporate motives are an inappropriate subject for expert testimony; and (2) Humphrey merely regurgitates select quotations without applying any discernible expert methodology.

1. Motive, intent, and state of mind are not proper subjects of expert testimony.

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Humphrey's opinion should be excluded because corporate motive is not a proper subject for expert testimony. The "opinions of [expert] witnesses on the intent, motives, or states of mind of corporations, regulatory agencies and others have no basis in any relevant body of knowledge or expertise." *Aya Healthcare Servs., Inc. v. AMN Healthcare, Inc.*, 2020 WL 2553181, at **5-6 (S.D. Cal. May 20, 2020) (quoting *Stone Brewing Co., LLC v. MillerCoors LLC*, 2020 WL 907060, at *4 (S.D.

Cal. Feb. 25, 2020)) aff'd, 9 F.4th 1102 (9th Cir. 2021). In Aya Healthcare the court excluded an expert opinion that set out "industry participants' interpretations of and reactions to certain of [defendant's] contract provisions." Id. at *5. The court reasoned that "[s]uch testimony intrudes on the province of the jury, who is capable of evaluating the same evidence and drawing conclusions without [the expert's] proffered testimony." Id. at *6. Here, too, the factfinder can draw its own conclusions about Intuitive's motive for the chip upgrade based on the evidence presented. Humphrey's own personal speculation adds nothing. See id.; see also Berman v. Freedom Fin. Network, LLC, 400 F. Supp. 3d 964, 972 (N.D. Cal. 2019) ("[T]he intentions of defendants . . . are outside [an expert's] expertise and not properly within the province of expert testimony."); In re Rezulin Prod. Liab. Litig., 309 F. Supp. 2d 531, 546-47 & nn. 38 & 40 (S.D.N.Y. 2004) (excluding expert testimony about defendant's intent, including profit motive for allegedly unlawful conduct).

Humphrey also has no qualifications to opine on corporate motives. Humphrey purports to be an expert in reverse engineering microelectronic devices, and he has studied ceramics engineering. *See* Cahoy Dec. Ex. 10 at 13:4-7; 22:11-13. He has no expertise that would qualify him to assess corporations' motives or intent. His opinions should be excluded for this reason too. *See A.B. v. Cnty. of San Diego*, 2020 WL 4431982, at *3 (S.D. Cal. July 31, 2020) (excluding testimony on intent, motive or state of mind of corporations because "[s]uch testimony has no basis in any relevant body of knowledge or expertise and is therefore inadmissible").

2. Humphrey summarizes record evidence without applying any expert methodology to his hand-picked examples.

Humphrey's speculation about Intuitive's supposed motives should be excluded for yet another reason: It does not apply any identifiable expert methodology, as opposed to his personal interpretation of out-of-context quotes from Intuitive emails and documents. *See* Cahoy Dec. Ex. 9 at ¶¶ 16, 48-59; Cahoy Dec. Ex. 12 at ¶ 14. The section on motive marches through Humphrey's interpretation of a handful of internal documents, which he contends demonstrate that "Intuitive's reason for employing the more robust encryption and security features for the X and Xi EndoWrists was to prevent modification

of the use counter." *See* Cahoy Dec. Ex. 9 § VI. A number of those documents post-date the launch of the X/Xi instruments by several years. *See id.* ¶¶ 41-42, 52, 55. And in others, Humphrey selectively excerpts some portions while omitting other portions that reflect Intuitive looking for a chip with larger memory than the S/Si chip. *See* Cahoy Dec. Ex. 9 ¶¶ 48-51; Cahoy Dec. Ex. 10 at 113:21-116:18. The section on purported motive leaves out any discussion of the X/Xi cybersecurity risk assessment that Intuitive performed and submitted to the FDA, *see* Cahoy Dec. Ex. 4 at ¶¶ 33-41, 52, and Humphrey lacks any experience with conducting cybersecurity reviews of new products, Cahoy Dec. Ex. 10 at 31:25-32:3.

Courts routinely reject this type of parroting of documents offered in the guise of expert testimony. For example, in *Department of Toxic Substances Control v. Technichem, Inc.*, this Court excluded an expert's opinions when he "d[id] no more than regurgitate information given to him by other sources He [did] not analyze his source materials so much as repeat their contents." 2016 WL 1029463, at *1 (N.D. Cal. Mar. 15, 2016) (Chhabria, J.). Likewise, in *Siqueiros v. General Motors LLC*, the court held that the expert's citation of deposition testimony and internal company documents "restate[d] nothing more than what is stated in the testimony or documents." 2022 WL 74182, at *9-10 (N.D. Cal. Jan. 7, 2022). Because the expert merely summarized the record and did not apply any methodology, his opinions invaded the province of the jury and were not appropriate under Rule 702. *Id.* Humphrey's opinions on motive should be similarly excluded. *See id.*; *see also Exeltis U.S. Inc. v. First Databank*, 2020 WL 7025089, at *5 (N.D. Cal. Nov. 30, 2020) ("[E]xpert testimony that merely summarizes the record evidence and gratuitously interprets it is improper.") (cleaned up).

B. Humphrey Lacks the Necessary Software Qualifications to Opine on the Feasibility of Breaking Encryption and Programming a Use Counter.

Humphrey also offers a number of new opinions on the feasibility of breaking the encryption and re-programming the use counter on an X/Xi EndoWrist. He lacks the qualifications to offer such opinions; and with his inability now to place reliance on Mandel, he has no basis for important precursors to this opinion.

Humphrey is not a software engineer. As he explained in his deposition, encryption is a type of software, and "[his] expertise tends to be more in the hardware, not the software side of things." Cahoy Dec. Ex. 10 at 124:2-124:22. "[P]rogramming of chips" likewise "isn't something that [his team] do[es] on a regular basis." *Id.* at 137:6-11. He therefore is not qualified to offer freestanding opinions on the feasibility of or resources involved in breaking the encryption of the X/Xi or re-programming the use counter. *See Maldonado v. Apple, Inc.*, 2021 WL 1947512, at *17 (N.D. Cal. May 14, 2021) (excluding testimony of an engineering expert who lacked expertise in the particular field of engineering at issue because "slapping the label 'engineering' on an expert or opinion is insufficient to show expertise across that expansive field") (collecting cases).

In *Rebotix*, the court allowed the opinions in Humphrey's original report to survive a *Daubert* challenge, but there he relied on an expert report from another expert, Gwen Mandel, a self-described cybersecurity consultant, for the software topics of encryption and programming. Ms. Mandel (who was the daughter of Rebotix's co-founder) proposed an approach she thought might work to break the encryption on the X/Xi to re-program the use counter; that approach was based on two key assumptions about the chip: (1) that data could not be encrypted or otherwise secured when at rest in the chip's memory, and (2) the entire chip was re-programmable in nature, so that Rebotix could directly alter the memory of the chip to re-set the use counter. Cahoy Dec. Ex. 9, Attachment 3 at ¶¶ 27, 39(b), 45, 47, 54, 62, 92. Relying on these assumptions, Humphrey opined that the first step of Ms. Mandel's approach to extract the data would be a "simple process," *Id.* ¶ 45, and that the subsequent step of re-programming the use counter "will be easier than resetting the usage counter on the S/Si EndoWrists," *id.* ¶ 47.

Humphrey no longer characterizes the process that would be needed to reset the use counter on an X/Xi EndoWrist as "simple." Indeed, he now appears to be walking away from his previous reliance on Ms. Mandel's report. When asked about the veracity of her key assumptions or whether they worked out in practice, Humphrey acknowledged that he is "not privy to any of the work that she's done for over a year and a half so I don't even know for sure whether she would still maintain that same position or not." Cahoy Dec. Ex. 10 at 70:14-71:3. He now believes that, "as compared to the encryption used for

the use counter of the Si EndoWrists, the Xi encryption requires substantially more time and resources to reverse engineer." *See* Cahoy Dec. Ex. 9 at ¶ 14. And he admits that he now does not know whether the two key premises of Ms. Mandel's approach are correct. *See* Cahoy Dec. Ex. 10 at 84:18-21 ("Q: So it's possible to program the data onto the [chip] such that it will be encrypted at rest? A: Yes, I think that's possible."); *id.* at 130:24-131:3 ("Q: So sitting here today, you don't know if the use counter is on a reprogrammable portion of the [chip] or on a non reprogrammable portion of the [chip]? A: No, I don't know.").⁴

At bottom, Humphrey has walked away from the opinions and approach he espoused in *Rebotix*, and he lacks the software expertise to identify any alternative approach for breaking the encryption on the X/Xi chip and re-programming the use counter. With the foundation he previously relied on now absent, and nothing offered to take its place, he is not qualified to offer opinions on the feasibility and resources involved in performing these functions. *See Maldonado*, 2021 WL 1947512 at *17.

C. Humphrey's Conflicting Opinions on the Timing of When X/Xi Resets Could Have Been Performed in the Past Should Be Excluded as Unreliable.

Although there is no evidence that a third-party company has a fully developed process to successfully reset an X/Xi EndoWrist, *see* Cahoy Dec. Ex. 9 at ¶¶ 34-35; *id.* Ex. 10 at 132:16-133:7; *id.* Ex. 8 at 38:9-39:12, Humphrey offers several conflicting hypothetical timeframes for when it allegedly would have been accomplished, but for Intuitive's conduct. *See id.* Ex. 9 at § V. Humphrey's shifting timeframe estimates stem from no reliable principle or method and should be excluded.

Humphrey's hypothetical timeframes are constantly changing, making his estimates unreliable on their face. For example, his report states that X/Xi resets would have been possible "at least as early as 2019." *See* Cahoy Dec. Ex. 9 at ¶ 15. But later he says they could have occurred "at any time in the last five years, if not earlier." *Id.* at ¶ 36. He separately notes that Restore began developing an X/Xi reset method in June 2022 and based on deposition testimony "expects to have a completed solution on

⁴ In fact, Ms. Mandel was wrong on both of these points. *See* Cahoy Dec. Ex. 4 (Martin Report) ¶ 77; *see also id.* Ex. 2 at 57:22-58:17. And, as of this date, there is no evidence that Rebotix, or anyone else, has a fully developed process to hack into the X/Xi chip and re-program the use counter. *See infra* § C.

the market in the third or fourth quarter of 2023," a projection he deems "reasonable" without any analysis. *Id.* ¶ 34. According to SIS's damages expert, Richard Bero, Humphrey apparently offered yet another differing time estimate for X/Xi resets – "January 1, 2021 or January 1 2022" – in a discussion with Bero, although Humphrey does not remember ever speaking with Bero. *See* Cahoy Dec. Ex. 7 at p. 5 n.19; *id.* Ex. 10 at 139:22-140:5; 142:12-15. Any expert methodology that produces such arbitrary and widely varying results cannot be the result of reliable "principles and methods." Fed. R. Evid. 702(c).

Humphrey offers no discernible methodology for his date ranges. They are passing assertions in his report that lack any support. When asked for the basis of the time estimate, the most Humphrey could offer was: "Just that there is nothing that – no evidence I've seen that inherently shows this work couldn't have been started much earlier." Cahoy Dec. Ex. 10 at 94:3-95:1. He could think of no other basis for the opinion. *Id.* Rule 702 does not permit such "*ipse dixit*" testimony. *Joiner*, 522 U.S. at 146.

V. CONCLUSION

Intuitive respectfully requests that the Court exclude all of Humphrey's opinions for the reasons stated above.

DATED: March 23, 2023 COVINGTON & BURLING LLP

By: <u>/s/ Kathryn E. Cahoy</u>
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